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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,478	02/25/2002	John L. Ricci	1065.36	4351

7590 12/27/2005

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/081,478	Applicant(s) RICCI ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005 and 12 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the invention of Group I (article for use in healing of wounds and repair of bone tissue defects), represented/embodied in claims 1, 3, 4, 6-8, and 11-16 in the reply filed on October 3, 2005 is acknowledged.

The traversal is on the ground(s) that “the two matrix examples provided by the Examiner are not equivalent to the instant method of using the article for repairing bone tissue defects”. Also, Applicants argue that: “the requirement in MPEP 806.4 states that the Examiner needs to show that the two inventions are distinct and independent”.

This is not found persuasive because MPEP 806.5(h), as indicated in form paragraph 5 of the Office Action of September 8, 2005, states: “*Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product*”. As the Examiner clearly indicated in said Office Action, the process for using the product as claimed can be practiced with another materially different product. Said “materially different product” could be a matrix having an upper surface/side seeded with soft tissue cells, and a bottom surface/side seeded with bone tissue cells. As an alternative, the method as claimed could be performed with a matrix having an upper surface/side comprising growth factors specific for soft tissue cells, and a bottom surface/side comprising growth factors specific for bone tissue cells.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on October 3, 2005.

Claim Objections

3. Claim 6 is objected to because of the following informality:

a. Regarding claim 6, please delete “collagen” (see line 5: second occurrence). Appropriate correction is required. This was addressed in the previous Office Action (April 27, 2004).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4, 6-8, and 11-16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Curtis et al. (US 5,833,641; cited in Applicants’ IDS).

Curtis et al. disclose an article for the healing of wounds and repair of tissue defects (see Abstract) comprising a flexible membrane/sheet (see Figure 1; column 3, line 55 to column 4, line 2) having an upper and a lower surface (see column 5, lines 10-13), each surface defining a substrate formed of a biologically-acceptable biodegradable material adapted to be resorbed in use (see column 2, lines 31-34; column 3, lines 23-40), each substrate having thereon means capable

of orienting cell growth comprising a microgeometry formed in said substrates (see column 4, lines 24-29), a microgeometry of an upper surface proportioned to a cell morphology of soft tissue cells and a microgeometry of a lower surface proportioned to a cell morphology of hard tissue cells (see column 5, lines 10-13; column 2, lines 35-46; column 3, line 55 to column 4, line 2; see entire document). Said membrane/sheet defines a width of between about 200 microns and about 500 microns (see column 3, lines 49-54). Said microgeometries comprise a pattern of grooves and ridges (see Figure 1; column 4, lines 30-67). Each of said microgeometries defining a dimension of about 1 micron to about 10 microns (see column 4, lines 35-44), depending on the targeted cell type (see column 4, lines 35-67).

Response to Arguments

6. Applicant's arguments filed May 12, 2005 (duplicate copy was filed on June 20, 2005) have been fully considered but they are not persuasive. With regards to Curtis et al. '641, Applicants argue that: "the claimed subject matter is not disclosed, taught, or suggested by the art of record". The Examiner respectfully disagrees.

a. It should be noted that, for both the surface pattern of the upper surface of the membrane and the surface pattern of the lower surface of the membrane, independent claims 1 and 11 claim a "microgeometry" of "grooves" and "ridges". In other words, there is no difference in shape between both "microgeometries". Also, for each "microgeometry", the claimed range of the width and height (depth) of the "grooves" and "ridges" of the upper surface overlaps the claimed range of the width and height (depth) of the "grooves" and "ridges" of the lower surface. Said upper and lower surface pattern of "grooves" and "ridges" having the claimed range of width and

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height (depth) is clearly disclosed, taught, or suggested by the art of record (see 102(b) rejection above). In other words, Curtis et al. '641 teach a flexible membrane having upper/lower surfaces, each one comprising a surface pattern of grooves and ridges as claimed in claims 1, 3, 4, 6-8, and 11-16, and said grooves/ridges having the same width and height (depth) dimensions as claimed in claims 1, 3, 4, 6-8, and 11-16.

b. With regards to the intended use limitations (i.e., “proportioned to a cell morphology of soft tissue cells” and “proportioned to a cell morphology of bone (hard) tissue cells”), it should be noted that Curtis et al. clearly disclosed, taught, or suggested applicability to gum heal after tooth replacement (see column 1, lines 22-24), several types of wounds (i.e., dentistry; see column 2, lines 47-58), and “ligament, tendon, muscle, blood vessel or other elongated structure which requires repair” (see column 3, line 66 to column 4, line 2).

c. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. This application contains claims 17-20 drawn to an invention nonelected with traverse in the Paper filed October 3, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-6:00 p.m.), first Friday of the bi-week off.

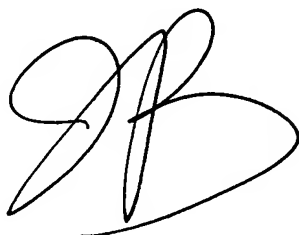

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to

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the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

December 17, 2005

A stylized, handwritten signature consisting of large, flowing loops and curves, likely representing the initials JGB.A handwritten signature in cursive script, appearing to read 'David H. Willse', with a long horizontal flourish extending to the right.

David H. Willse
Primary Examiner